PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3198
Manufacturer	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

Applied legislative act

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds	
Classification	Risk Class	Rule
	Class IIb	Rule 4 | main paragraph + 2nd indent
Conformity Assessment Procedure	Article 52 (4) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER, Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003198L5	
EMDN	Code	Term
	M040499	DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
GMDN	58475	Sodium chloride dressing
UMDNS	15-216	Verband, sonstige (dressings, other)

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090

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ppa.

Jochen Bauer
Vice President R&D Wound Care & Consumer Health

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid from: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description	
609220	HydroClean 4cm P10 K6	
609222	HydroClean 4x8cm P10 K6	
609224	HydroClean 5,5cm P10 K6	
609226	HydroClean 7,5x7,5cm P10 K6	2.0
609228	HydroClean 10x10cm P10 K6	2.0
609230	HydroClean 8x14cm oval P10	
609232	HydroClean 10x17cm P10	
609320	HydroClean 4cm P3 K12	
609322	HydroClean 4x8cm P3 K12	

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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